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DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

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Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

Telephone: 504-253-4500
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January 7, 2000

WARNING LETTER NO. 2000-NOL-11

FEDERAL EXPRESS
OVERNIGHT DELIVERY

William D. LeBlanc, President
LeBlanc's Cajun Boudin & Food Company, Inc.
44437 Highway 429
St. Amant, Louisiana 70774

Dear Mr. LeBlanc:

On August 3-4, 1999, U.S. Food and Drug Administration (FDA) investigators conducted an inspection of your frozen seafood pies processing facility, located at 44437 Highway 429, St. Amant, Louisiana. The inspection was conducted to determine compliance with FDA's seafood processing regulations, Title 21, *Code of Federal Regulations* (CFR), Part 123 and the Current Good Manufacturing Practice (CGMP) regulations for foods CFR, Part 110. Our investigators documented numerous deviations from these regulations. This causes your frozen pies (shrimp and crawfish), to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act.

The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur. These are the kinds of measures that prudent processors already take. HACCP provides a systematic way of taking those measures that demonstrates to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During the August 1999 inspection, the FDA investigators observed shortcomings in your system that were similar to those pointed out in the March 25, 1998, inspection, and stated in the untitled letter sent to your firm on July 8, 1998. The FDA investigators also provided your firm with a copy of the Domestic Seafood HACCP Report (Form FDA 3501) and the Form FDA 483, which presents their evaluation of your firm's performance regarding various aspects of the

HACCP and CGMP requirements. The Form FDA 483 is enclosed for your review. The observations of concern to us are as follows:

- Failure to have and implement a HACCP plan for your products (shrimp and crawfish pies). Title 21, CFR, Part 123.6(a) requires that you conduct a hazard analysis for each of the seafood products that you process. When you identify one or more food safety hazards associated with a product, Title 21, CFR, Part 123.6(b) requires you to have and implement a HACCP plan for the control of these hazards. Title 21, CFR, Part 123 6(c) details what a HACCP plan shall include and Title 21, CFR, Part 123.10 provides the minimal requirements for the individual who develops and maintains the HACCP plan and associated documentation.

  We are particularly concerned with your failure to implement HACCP plans to control the food safety hazard of sulfites in shrimp and pathogen growth due to potential time and temperature abuse in your shrimp and crawfish stuffings.

- Failure to monitor and maintain monitoring records to document the adequacy of the cooking process for the shrimp and crawfish stuffings, as required by Title 21, CFR, Part 123.6(b).

  You should first perform a cook study to demonstrate that the cook is adequate for each of these products and this process. The study must include the time and temperature of the cook, the batch size, the size and type of equipment, and the type of ingredients, taking into consideration the raw ingredients and seasonings used.

  You must also maintain records of the cooking time and maximum temperature achieved for each process to document that you are controlling the process.

- Failure to control the hazard associated with the cooling step in the manufacture of your shrimp or crawfish stuffing, as required by Title 21, CFR, Part 123.6(b).

  In many foods, rapid cooling after the cook step is essential in preventing spores of *C. perfringes* and *Bacillus cereus* from forming. The initial stage of cooling after the cook, during which the product is held at temperatures above 140 degrees F, would not require time/temperature controls. But when significant handling occurs before or during the cooling process, and when the product comes in contact with equipment that was not heated (or cooked) with the product, you need to identify cooling as a critical control point (CCP) for this hazard.

- Failure to monitor sanitation practices and conditions adequately to ensure the safety of product, as required by Title 21, CFR, Part 123.11(b).

  Specifically, your firm is not keeping documentation to assure that employees are in good health, the food plant is free of pests, and toxic compounds are properly labeled and stored. Our investigators observed one of your employees entering the crawfish processing room and processing crawfish pies without washing or sanitizing her hands, another employee wearing fingernail polish while processing crawfish pies, and a water hose that was previously resting

on the floor was placed into the vat used to cook the rice and the stuffing for the crawfish pies.

As the principal corporate officer, it is your responsibility to assure that your processing plant is operating in compliance with the applicable laws and regulations. It is also your responsibility to assure not only that the current objectionable conditions are corrected, but that adequate policies and procedures are implemented to prevent a recurrence of the problems.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the applicable regulations. You should take prompt action to correct these deviations. Failure to promptly correct the deviations may result in regulatory action without further notice. These include seizure and/or injunction.

We are aware that at the close of the inspection you made a verbal commitment to correct the observed deficiencies. Our investigators documented this commitment by annotation of the FDA Form 483. However, you should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply, relating to these concerns, should be addressed to the U.S. Food and Drug Administration, Attention: Mr. Jose R. Hernandez, Compliance Officer, 6600 Plaza Drive, Suite 400, New Orleans, Louisiana 70127. If you have any questions regarding the implementation of the HACCP regulations, you may contact Mr. Hernandez at (504) 253-4500.

Sincerely,

for Howard E. Lewis
Acting District Director
New Orleans District

Enclosure: Form FDA 483